

records, and to interview any employees who may be knowledgeable of quality management processes associated with the production of the CPDM. Audits may be conducted either on an occasional or periodic basis or in response to quality-related complaints or concerns.

(c) *Applicant remediation of quality management deficiencies.* An applicant or approval holder must correct any quality management deficiency identified by an audit within a reasonable time as determined by NIOSH. Failure to correct a deficiency may result in NIOSH disapproval of a pending application or, in the case of an approved device, revocation of approval until NIOSH determines that the deficiency is corrected.

§ 74.10 Operating and maintenance instructions.

(a) *Contents.* The manufacturer must include operating and storage instructions and a maintenance and service life plan with each new CPDM device sold. These documents must be clearly written.

(1) Operating and storage instructions must include:

(i) An explanation of how the CPDM works;

(ii) A schematic diagram of the CPDM;

(iii) Procedures for wearing and use of the CPDM;

(iv) A one page "quick start guide" that will enable a novice to start and operate the CPDM.

(v) Procedures for calibration of the CPDM;

(vi) Procedures for inspecting the operating condition of the CPDM;

(vii) Procedures and conditions for storage, including the identification of any storage conditions that would likely impair the effective functioning of the CPDM; and

(viii) Procedures and conditions of use, including identification of any conditions of use that would likely impair the effective functioning of the CPDM.

(2) The maintenance and service life plan must address:

(i) Conditions that should govern the removal from service of the CPDM; and

(ii) Procedures that a user or others should follow when inspecting, performing maintenance and calibration, and determining when the CPDM should be removed from service.

(b) *Submission to NIOSH for approval.* A copy of the instructions and plan under paragraph (a) of this section shall be submitted to NIOSH with the application for approval of the CPDM and if substantive changes are made to the approved device or approved instructions.

§ 74.11 Tests of the continuous personal dust monitor.

(a) *Applicant testing.* The applicant shall conduct tests to determine whether a CPDM that is submitted for approval under these regulations meets the requirements specified in §§ 74.7–74.8 of this part, with the exception of durability testing, which shall be conducted by NIOSH as specified in § 74.7(g) of this part. Applicant testing shall be performed by an independent testing entity approved by NIOSH.

(b) *NIOSH testing assistance.* NIOSH will provide consultation to the applicant to identify and secure necessary testing services for meeting the requirements specified in §§ 74.7–74.8 of this part. Applicants must submit testing protocols to NIOSH prior to testing to verify that the testing protocols adequately address the requirements.

(c) *Reporting of applicant testing results.* The applicant shall include the results from testing specified under paragraph (a) of this section when submitting the application under § 74.13 of this part to NIOSH.

(d) *Intrinsic safety testing.* The applicant shall submit the CPDM to MSHA for testing and evaluation, pursuant to 30 CFR 18.68, to determine whether the electronic components of the CPDM submitted for approval meet the applicable permissibility provisions.

Subpart D—General Requirements for All Devices

§ 74.12 Conduct of tests; demonstrations.

(a) Prior to the issuance of a certificate of approval, only personnel of MSHA and NIOSH, representatives of the applicant, and such other persons

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as may be mutually agreed upon may observe the tests conducted. MSHA and NIOSH shall hold as confidential, and shall not disclose, principles of patentable features, nor shall MSHA or NIOSH disclose any details of the applicant's drawings or specifications or other related material.

(b) After the issuance of a certificate of approval, MSHA or NIOSH will conduct such public demonstrations and tests of the approved device as MSHA or NIOSH deem appropriate, and may reveal the protocols and results of testing considered for the approval of the device. The conduct of any additional investigations, tests, and demonstrations shall be under the sole direction of MSHA and NIOSH and any other persons shall be present only as observers.

§ 74.13 Applications.

(a) Testing of a CMDPSU will be performed by NIOSH, and testing of the pump unit of the CMDPSU will be conducted by MSHA. The applicant must submit a written application in duplicate to both NIOSH and MSHA. Each copy of the application must be accompanied by complete scale drawings, specifications, and a description of materials. Ten complete CMDPSUs must be submitted to NIOSH with the application, and one pump unit must be submitted to MSHA.

(b) Testing of a CPDM will be performed by the applicant as specified under § 74.11. The applicant must submit a written application in duplicate to both NIOSH and MSHA. Each copy of the application must be accompanied by complete scale drawings, specifications, a description of materials, and a copy of the testing protocol and test results which were provided by an independent testing entity, as specified in § 74.11(a). Three complete CPDM units must be sent to NIOSH with the application, and one CPDM device must be sent to MSHA.

(c) Complete drawings and specifications accompanying each copy of the application shall be fully detailed to identify the design of the CMDPSU or pump unit thereof or of the CPDM and to disclose the dimensions and materials of all component parts.

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§ 74.14 Certificate of approval.

(a) Upon completion of the testing of a CMDPSU or the pump unit or after review of testing protocols and testing results for the CPDM, NIOSH or MSHA, as appropriate, shall issue to the applicant either a certificate of approval or a written notice of disapproval. NIOSH will not issue a certificate of approval unless MSHA has first issued a certificate of approval for either the pump unit of a CMDPSU or for the CPDM. If a certificate of approval is issued, no test data or detailed results of tests will accompany such approval. If a notice of disapproval is issued, it will be accompanied by details of the defects, resulting in disapproval, with a view to possible correction.

(b) A certificate of approval will be accompanied by a list of the drawings and specifications covering the details of design and construction of the CMDPSU and the pump unit, or of the CPDM, as appropriate, upon which the certificate of approval is based. The applicant shall keep exact duplicates of the drawings and specifications submitted to NIOSH and to MSHA relating to the CMDPSU, the pump unit thereof, or the CPDM, which has received a certificate of approval. The approved drawings and specifications shall be adhered to exactly in the production of the certified CMDPSU, including the pump unit or of the CPDM, for commercial purposes. In addition, the applicant shall observe such procedures for, and keep such records of, the control of component parts as either MSHA or NIOSH may in writing require as a condition of approval.

§ 74.15 Approval labels.

(a) Certificate of approval will be accompanied by photographs of designs for the approval labels to be affixed to each CMDPSU or CPDM, as appropriate.

(b) The labels showing approval by NIOSH and by MSHA shall contain such information as MSHA or NIOSH may require and shall be reproduced legibly on the outside of a CMDPSU or CPDM, as appropriate, as directed by NIOSH or MSHA.